

AMENDMENTS TO THE DRAWINGS

FIGURES 1-29 have been amended to include legible number and reference characters and well-defined numbers and letters as suggested in the Office Action. Replacement drawing sheets are attached to this amendment.

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REMARKS

This paper is responsive to the Office Action dated December 18, 2008. Claims 23, 25-46 are currently pending. Claims 23, 25, and 30 have been amended. Claim 24 is canceled. Support for all new and amended claims can be found in the specification and no new matter has been added by these amendments. Reconsideration and allowance of the claims in view of the amendments and the following remarks is respectfully requested.

I. Oath/Declaration

The oath or declaration was said to be defective because it does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be "material to patentability as defined in 37 C.F.R. § 1.56." Rather, the oath as submitted specifies instead, "material to examination," which is said to be improper.

Applicant respectfully submits that the oath/declaration in the present application is subject to a Notice dated January 22, 2008, from Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. This Notice attached as Appendix A, indicates that for pending applications the Office Action is *sua sponte* waiving the express language requirement of 37 C.F.R. § 1.63(b)(3) if the oath or declaration contains the "material to examination" or "in accordance with § 1.56(a)" language, or both, and was filed prior to June 1, 2008. Applicant respectfully submits that under the foregoing Notice, the oath/declaration in the present application is acceptable to the Office.

II. Drawings

The drawings were objected to because lines, numbers, and letters are not uniformly thick and well defined; and numbers and reference characters are not plain and legible for all figures. In response, applicant submits herewith replacement drawing sheets that include figures amended in accordance with the suggestions made in the Office Action.

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In addition, the Office Action indicated that "cooperating tapered surfaces" of the collet lock sleeve and collet fingers are not shown in the drawings as recited in Claims 28 and 29. Applicant respectfully disagrees. Claims 28 and 29 each recite "said collet lock sleeve and said collet fingers are respectively provided with cooperating tapered surfaces." Such features are well depicted in various figures of the present application, for example in FIGURES 19, 20, and 23 (e.g., the collet lock sleeve (78) cooperated with a tapered head area (76A) of a collet finger (76)). See also page 22, lines 19-31. Further, applicant notes that the collet finger and the head area of the collet finger are depicted in detail in FIGURE 13.

Accordingly, applicant respectfully submits that the objections to the drawings be removed.

III. Rejections under 35 U.S.C. § 112, first paragraph

Claims 28 and 29 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action states that "the cooperating tapered surfaces of the collet lock sleeve and collet fingers are only recited on page 5, lines 5-7, of the specification. It is not explained which surfaces should be cooperating and tapered and how they are meant to cooperate with each other." (Office Action, page 4).

As mentioned above in connection with Section II, the features recited in Claims 28 and 29 are depicted and described throughout the specification, in particular at page 22 lines 19-31 and in FIGURES 13, 19, 20, and 23. Accordingly, applicant submits that Claims 28 and 29 are allowable and request that the rejection of Claims 28 and 29 under 35 U.S.C. § 112, first paragraph be withdrawn.

IV. Rejections under 35 U.S.C. §102 and 35 U.S.C. § 103

Claims 23 and 32 were rejected under 35 U.S.C. § 102(b) as being anticipated by Schiff et al. (U.S. Patent No. 5,865,795, "Schiff"). Claims 24-31 were rejected under 35 U.S.C.

§ 103(a) as being unpatentable over Schiff in view of Landau et al. (U.S. Patent No. 6,752,781, "Landau"). Applicant respectfully disagrees. Claim 23 is amended to include an element recited in Claim 24. Claim 24 has been cancelled.

1. Independent Claim 23

As amended, Claim 23 recites,

A needleless injection device, comprising:

a cylinder for medicament having an injection nozzle at a forward end thereof and an opening at its rearward end;

a piston sliding in the cylinder through said open end, in use, to drive the medicament through the nozzle;

a ram to drive the piston into the cylinder and having a longitudinal axis; and

an energy accumulator to drive the ram when discharged and disposed between the ram and a discharge assembly, a rear end of the ram extending into said discharge assembly;

wherein the discharge assembly comprises a retention member fixed in the assembly, said retention member having a plurality of retention elements spaced around and adapted to locate on the ram when in a charged position of the ram, and a release ring surrounding said retention elements to prevent radial outward displacement thereof and discharge of the ram;

wherein axial displacement of said release ring releases said retention elements and causes discharge of the ram by said accumulator;

wherein said retention elements are integral with said retention member and each has an enlarged head which can move into and out of engagement with a groove or recess on the ram by deformation of the material of said retention member; and

wherein said retention member comprises a collet having radially spreadable fingers, which collet in use moves between said first position in which said fingers engage with said ram and said second position in which said fingers spread radially out of engagement with said ram.

These elements and features are not taught, suggested, or disclosed by the cited references, alone or in combination. For example, Schiff fails to teach at least "retention

elements are integral with said retention member and each has an enlarged head which can move into and out of engagement with a groove or recess on the ram by deformation of the material of said retention member," as recited in Claim 23. In general, Schiff is directed to a device having a retention member comprise ball bearings (see Fig. 3, ball bearings 64) which still suffer a "rattle" (i.e. reverberation) problem that the retention member as claimed is used to solve.

In the Office Action, it is indicated that "ball bearing" and "guide" of Schiff are respectively equivalent to "retention elements" and "retention member" as recited in Claim 23. Applicant respectfully asserts that the ball bearings as disclosed in Schiff are patentably different from the retention elements as claimed since the ball bearings are not integral with the guide, while the needleless injection device of Claim 23 requires that "retention elements are integral with said retention member." Applicant asserts that the ball bearings and the guide of Schiff are clearly independent and separable components since, according to Schiff, the ball bearings are received in the holes (or apertures) of the guide for retention of a plunger and are removed into annular space for allowing the plunger to move distally. See Col. 7 lines 5-49. Accordingly, it cannot be said that the ball bearings as disclosed in Schiff are "integral with" the guide.

For at least this reason, Schiff fails to teach or suggest "retention elements are integral with said retention member and each has an enlarged head which can move into and out of engagement with a groove or recess on the ram by deformation of the material of said retention member," as recited in Claim 23.

Moreover, as conceded by the Office Action, Schiff fails to teach or suggest "said retention member comprises a collet having radially spreadable fingers, which collet in use moves between said first position in which said fingers engage with said ram and said second position in which said fingers spread radially out of engagement with said ram," as recited in Claim 23. (Office Action, page 6).

Another reference, Landau, does not remedy these deficiencies of Schiff as Landau does not teach, suggest or disclose anything related to the retention member as claimed. Landau is directed to a complex needleless injection device where the energy source provides forward force using pressurized gas and the control of this pressurized gas is achieved using a valved chamber. See Figures 5 and 6. However, there are no features in the valved chamber equivalent to a "retention member" and "release ring" as recited in Claim 23. Rather, Landau discloses a ratchet arrangement where, for example, *the ram* has "an *axial array of plural circumferential teeth*" (emphasis added; Col. 10 line 43) with which "an internally toothed collet member 96" can engage. See also Figure 9. Such arrangement is "characterized as a linear ratchet mechanism." See Col. 11, line 44. In Landau, the ratchet mechanism is apparently disclosed as "a lost motion preventer" and is an alternative embodiment to the lost motion preventer shown in Figures 7 and 8.

Applicant submits that the lost motion preventer (the ratchet mechanism) is fundamentally different from the retention member as claimed. In the present application, the retention member and release ring are provided to prevent outward displacement of the retention elements and premature discharge of the ram, resulting from the forward force supplied by the energy source. In Landau, the lost motion preventer is provided *to insure that the variable-volume chamber is substantially at its minimum volume* at the beginning of each hypodermic jet injection event, regardless of the axial position of the ram and thus *utilizing pressurized gas from cartridge at its highest possible pressure*, and preventing or minimizing expansion throttling of pressurized gas from this cartridge as this gas expands into chamber. See Col. 8, lines 41-65.

While rejecting Claim 24 under 35 U.S.C. § 103, the Office Action points to Landau at Col. 10, line 64, and Figures 9 and 10 as disclosing a collet having radially spreadable fingers, which collet in use moves between said first position in which said fingers engage with said ram

and said second position in which said fingers spread radially out of engagement with said ram that is included in amended Claim 23. Office Action, page 6.

Applicant asserts that the relied-upon portions of Landau are merely directed to the ratchet mechanism. As discussed above, while Landau discloses a collet (96) with a "jaw space" for engagement with a selected groove from multiple grooves formed on the ram, Landau fails to teach the retention member or retention elements as claimed.

The Office Action further states that it would have been obvious to one of ordinary skill in the art at the time the invention was made "to replace Schiff's retention member with Landau's equivalent collet with radially spreadable fingers to achieve the predictable result of engaging the ram." However, the Office Action does not identify any particular *reason* that would have prompted one of ordinary skill and creativity to modify the cited references to arrive at the claimed invention. As taught by the Supreme Court in the *KSR* decision, the analysis supporting a rejection under Section 103 should be made explicit.

Further, even if, *arguendo*, the teaching of Schiff and Landau are combined as asserted by the Office Action, the claimed invention would not result. The ram disclosed in Schiff does not include any grooves or an axial array of plural circumferential teeth which is necessary for the collet of Landau to engage with the ram in order to operate properly. Thus, if the collet with a jaw space disclosed in Landau is used in the injection device disclosed in Schiff replacing the retention member as asserted in the Office Action, the combined device will not be operable for retention of the ram.

In view of the above, the cited references (e.g., Schiff and Landau), alone or in combination, fail to teach or suggest all elements recited in amended Claim 23. Thus, Claim 23 is allowable. Applicant respectfully requests that the rejection with regard to Claim 23 be withdrawn.

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Dependent Claims 25-31

Claims 25-31 depend from Claim 23. Thus, Claims 25-31 include all elements recited in Claim 23. As discussed above, Schiff and Landau fail to teach, suggest, or disclose all elements of Claim 23 and thus also fail to teach all elements of Claims 25-31. Accordingly, Claims 25-31 are allowable in view of their dependency from allowable Claim 23. Applicant respectfully requests that the rejection of Claims 25-31 under 35 U.S.C. § 103 be withdrawn.

Dependent Claims 39, 40, 45 and 46

The Office Action rejected Claims 39, 40, 45, and 46 under 35 U.S.C. § 103(a) as being unpatentable over Schiff in view of Weston (U.S. Patent No. 5,891,086).

Claims 39, 40, 45, and 46 depend from Claim 23. The rejection of Claims 39, 40, 45, and 46 is premised on the assertion that Schiff discloses the features recited in amended Claim 23 and Weston discloses the remaining features of Claims 39-43, 45, and 46. As discussed above, however, Schiff and Landau, alone or in combination, do not disclose or suggest all elements recited in amended Claim 23. As best understood, Weston does not provide any teaching or suggestion that would remedy this deficiency. Therefore, the rejection is based on a flawed premise and cannot be maintained. Accordingly, applicant respectfully requests withdrawal of the rejection of Claims 30, 40, 45, and 46.

Dependent Claims 41-43

The Office Action rejected Claims 41-43 under 35 U.S.C. § 103(a) as being unpatentable over Schiff and Weston and in view of Slate (U.S. Patent No. 6,669,664). Claims 41-43 depend from Claim 40 which depends from Claims 39 and 23. The rejection of Claims 41-43 is premised on the assertion that Schiff and Weston disclose the features recited in Claim 40 and Slate discloses the remaining features of Claims 41-43. As discussed above, however, Schiff, Landau, and Weston, alone or in combination, do not disclose or suggest all elements recited in

Claim 40. As best understood, Slate does not provide any teaching or suggestion that would remedy this deficiency. Therefore, the rejection is based on a flawed premise and cannot be maintained. Accordingly, applicant respectfully requests withdrawal of the rejection of Claims 41-43.

Thus, withdrawal of the rejection of Claims 41-43 under 35 U.S.C. § 103(a) is respectfully requested.

Allowable Subject Matter

Applicant wishes to thank the Examiner for indicating that Claims 33-38 and 44 would be allowable if rewritten in independent form including all of the limitations of the base claim and intervening claims. In the Office Action, Claims 33-38 and 44 were objected to as being dependent upon a rejected base claim. Claims 33-38 and 44 directly or indirectly depend from allowable Claim 23. Thus, Claim 33-38 and 44 are further allowable for the at least same reason. Applicant respectfully requests that the objections be removed.

CONCLUSION

In view of the foregoing remarks, applicant respectfully submits that the above-referenced patent application is now in condition for allowance. Reconsideration of the application and allowance of the pending claims are solicited. If the Examiner has any questions, the Examiner is invited to contact the undersigned at the number provided below.

Respectfully submitted,

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**Duty of Disclosure Language Set Forth in Oaths or Declarations
Filed in Nonprovisional Patent Applications**

Summary:

The United States Patent and Trademark Office (Office) will no longer accept as complying with 37 CFR 1.63(b)(3) an oath or declaration that does not acknowledge a duty to disclose information material to patentability as defined in 37 CFR 1.56. All oaths or declarations filed on or after June 1, 2008, will be required to include the language expressly set forth in 37 CFR 1.63, including that in 37 CFR 1.63(b)(3). This notice applies to oaths or declarations filed in all nonprovisional patent applications, including reissue applications.

Background:

Current 37 CFR 1.63 sets forth the requirements for an oath or declaration filed in a nonprovisional patent application. 37 CFR 1.63(b)(3) sets forth what the person making the oath or declaration must state when acknowledging the duty of disclosure. Specifically, 37 CFR 1.63(b)(3) requires persons making an oath or declaration to state that they acknowledge their duty to disclose to the Office all information known to the person to be “material to patentability as defined in § 1.56.” This language is incorporated in: 37 CFR 1.153, which sets forth the requirements for an oath or declaration in a design application; 37 CFR 1.162, which sets forth the requirements for an oath or declaration in plant patent applications; and 37 CFR 1.175 which sets forth the requirements for an oath or declaration in a reissue application.

In 1992, the Office amended 37 CFR 1.63 to conform to amendments made in 37 CFR 1.56. See Duty of Disclosure, 57 FR 2021 (January 17, 1992) (final rule). The amendments to 37 CFR 1.63(b)(3) resulted in “material to patentability as defined in § 1.56” replacing “material to the examination of the application in accordance with § 1.56(a).” Despite this amendment to 37 CFR 1.63(b)(3), some applicants in their oaths or declarations continue to use “material to the examination of the application” in place of “material to patentability,” and “in accordance with § 1.56(a)” in place of “as defined in § 1.56.” In response to proper objections made during the examination of pending patent applications, practitioners have argued that the oaths and declarations executed by applicants with the outdated language in question are proper and meet the requirements set forth in 37 CFR 1.63 in view of Comment 38 and the accompanying Reply in the 1992 Final Rule. See Duty of Disclosure at 2027. Additionally, these practitioners have argued that the outdated language should be accepted because the Office has not routinely enforced strict compliance with current 37 CFR 1.63, as evidenced by the number of pending patent applications and issued patents containing oaths or declarations with the outdated “material to examination” and “in accordance with 37 CFR 1.56(a),” language.

Revised Procedure:

With this Notice, the Office is putting applicants and their representatives on notice that compliance with the express language of 37 CFR 1.63 will now be required. Additionally, to the extent the Reply to Comment 38 in the 1992 Final Rule authorized the continued use of the “material to examination” and “in accordance with 37 CFR 1.56(a),” language, this authorization it is hereby rescinded, and reliance on the Reply to Comments 38 will no longer be accepted. If an oath or declaration filed on or after June 1, 2008, does not include the express language set forth in 37 CFR 1.63(b)(3), the Office will object to the oath or declaration as failing to comply with 37 CFR 1.63. A supplemental oath or declaration pursuant to 37 CFR 1.67 will then be required.

For pending applications, the Office is hereby *sua sponte* waiving the express language requirement of 37 CFR 1.63(b)(3), where the oath or declaration was filed prior to June 1, 2008. The express language of 37 CFR 1.63(b)(3) is waived only to the extent necessary such that an oath or declaration containing the “material to examination” or “in accordance with § 1.56(a)” language, or both, will be accepted as acknowledging the applicant’s duty to disclose information “material to patentability” as defined in 37 CFR 1.56.

For continuing applications filed under 37 CFR 1.53(b), other than continuation-in-part applications, the Office will accept an oath or declaration that contains the outdated language if the oath or declaration otherwise complies with 37 CFR 1.63, and either: (1) was filed prior to June 1, 2008; or (2) is being filed in a continuation or divisional application in which a claim for benefit under 35 U.S.C. 120 has been made to a prior-filed copending nonprovisional application, and the oath or declaration is a copy of the previously accepted oath or declaration that was filed prior to June 1, 2008.

For issued patents, the Office is hereby waiving *nunc pro tunc* the express language requirement of 37 CFR 1.63(b)(3), where the oath or declaration was filed prior to June 1, 2008. As stated above, the express language of 37 CFR 1.63(b)(3) is waived only to the extent necessary such that an oath or declaration containing the “material to examination” or “in accordance with § 1.56(a)” language, or both, will be accepted as acknowledging the applicant’s duty to disclose information “material to patentability” as defined in 37 CFR 1.56. Any supplemental oath or declaration filed for an issued patent may simply be placed in the patent application file without review or comment.


While not required, patentees and applicants are free to submit newly executed oaths or declarations with the language expressly set forth in current 37 CFR 1.63(b)(3), in accordance with 37 CFR 1.67.

Applicants are advised that, notwithstanding the waiver in the preceding paragraphs, an applicant who has not disclosed information that is material to patentability as defined in current 37 CFR 1.56, because it was believed that the information was not “material to examination,” should disclose such information in order

to discharge the applicant's duty of disclosure as required by 37 CFR 1.56, and should file a supplemental oath or declaration acknowledging that duty of disclosure.

Questions about this notice may be directed to the Office of Patent Legal Administration at (571) 272-7701 or electronic mail message to PatentPractice@uspto.gov.

Date: 11/22/08



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